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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,220	01/18/2002	David P. Kanios	NOPH/120/JGK	7179

30527 7590 09/25/2003

NOVEN PHARMACEUTICALS, INC.  
11960 S.W. 144TH STREET  
MIAMI, FL 33186

EXAMINER

ARNOLD III, TROY G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 09/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/051,220

Applicant(s)

KANIOS ET AL.

Examiner

Troy Arnold

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2-6 and 11-13 is/are rejected.
- 7) ☒ Claim(s) 7-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merrell, US Patent No. 6,102,198. Merrell teaches all the limitations of claim 2 except "a transdermal system comprising.....a drug." Merrell teaches compounds such as NaCl, KI, KNO<sub>3</sub>. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the compounds taught by Merrell with transdermal systems comprising a drug, as his system appears perfectly suited to containing such items, if they are being shipped in bulk for example. (Merrell teaches a product packaging system 10 consisting essentially of a sealable product package 12,13 substantially moisture impermeable comprising a barrier material configured as claimed (see column 3 beginning line 29), one or more pouches 23 consisting essentially of a packaging material which is permeable to moisture and non-absorbing or reactive (see column 4 beginning line 1) and a transdermal system C comprising a drug in a non-aqueous carrier and being sealed within a pouch 23, a desiccant 27, wherein the pouch and the desiccant are sealed within the package.) Regarding claim 3, see column 3 beginning at line 29. Regarding claim 4, see items 12 and 13. Merrell

teaches all the limitations of claim 5 except the cover being sealed to the container by heat or adhesive. Merrell teaches sealing with a band or tape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to seal the cover 13 of Merrell to the container 12 with a heat or adhesive seal in order to make a more moisture-proof seal. Heat and adhesive seals are obvious and well-known in the packaging arts. Merrell clearly teaches the limitations of claim 6. Regarding claim 11, the sealed pouch 23 of Merrell will be child resistant, interpreting the term as broadly as is reasonable. Regarding claim 12, it would have been obvious to one of ordinary skill in the art to fill Merrell's pouch with a transdermal system comprising a chiral drug, as noted above. Regarding claim 13, see column 5, beginning line 58.

Claims 2-5, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilking, US Patent No. 5,698,217. Wilking teaches all the limitations of claim 2 except one or more pouches and the transdermal system being sealed within the pouches. Wilking teaches a system which is the full functional equivalent of that claimed. His transdermal system 32,34,36 is separated from the desiccant 20 by a moisture permeable barrier which acts like a pouch. It would have been obvious to one of ordinary skill in the art at the time the invention was made to fully enclose the transdermal system of Wilking in a pouch for the purpose of providing a second layer of protection against contamination when the package is opened. Regarding claim 3, see column 4, beginning line 47. Regarding claim 4, items 14 and 16. Regarding claim 5, see column 4, line 44. Wilking clearly teaches the limitations of claim 12, and claim 13 appears to be taught as well.

***Allowable Subject Matter***

Claim 1 is allowed.

Claims 7-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Troy Arnold whose telephone number is 703-305-0621. The examiner can normally be reached on Tuesday-Thursday, 9:30-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 703-308-2672. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Troy Arnold  
Examiner  
Art Unit 3728

TGA



Mickey Yu  
Supervisory Patent Examiner  
Group 3700